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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,491	06/15/2006	Elisabetta Bianchi	ITR0054P	4014
210 MERCK P O BOX 2000 RAHWAY, NJ 07065-0907	7590 08/30/2010		EXAMINER PENG, BO	
			ART UNIT 1648	PAPER NUMBER
			MAIL DATE 08/30/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/583,491	Applicant(s) BIANCHI ET AL.	
	Examiner BO PENG	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-62 is/are pending in the application.
- 4a) Of the above claim(s) 48-50 and 53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-47, 51, 52 and 54-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 37-62 are pending. Claims 48-50 and 53 have been withdrawn. Claims 37-47, 51, 52 and 54-62 are considered in this Office action.

Claim Objection

2. **(Prior objection-withdrawn)** The objection to Claim 39 for being dependent on itself **is withdrawn** in view of the amendment to the claim.
3. **(New objection)** Claims 51 is dependent on withdrawn Claim 50. Correction is required.

Claim Rejections - 35 USC § 112, second paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **(Prior rejection-withdrawn)** The rejection of Claims 37-47, 51, 52 and 54-62 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to define “peptide load”, **is withdrawn** in view of Applicant’s argument.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. **(Prior rejection-maintained)** The rejection of Claims 37-47, 51, 52 and 54-62 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, **is**

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maintained for the reason of record.

In response to Applicant's argument:

8. Applicants argue that the specification provides adequate teaching for one skilled in the art to use the claimed methods. The claimed methods specify that peptide load and/or solubility are increased because of the peptide modification. **Those modified peptides that do not meet this claim limitation are outside of the scope of the claims.** One skilled in the art could determine, using routine techniques, whether or not a peptide c-conjugate pair falls within the scope of the claims or not. An invention is enabled even though the disclosure may require some routine experimentation to practice the invention. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802

9. Applicants' argument is considered, but found unpersuasive. Applicants appear to argue the claimed method is enabled. However, the claims are rejected as failing to comply with the written description requirement, not enablement requirement. In *Regents of the University of California v. Eli Lilly & Co.* the court stated: "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, **where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...**") (Emphasis added) *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398. Moreover, MPEP § 2163 states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed

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sequence." MPEP § 2163 does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. In the present case, the scope of the claims is extremely broad, which encompasses making peptide-carrier conjugates of any structures by modifying the pI of a peptide and introducing "a non-naturally occurring sequence", so that the resulting peptide-carrier has increased peptide load and solubility. However, as indicated the previous Office action, the possible variations of peptides and carriers, in both structures and properties, are enormous. Although the specification shows 5 modified HA peptides (15-21-mers) conjugated to OMPC carrier, the specification lacks sufficient variety of species to reflect the variance of peptide-carrier conjugates encompassed in the scope of the claims. Instead, the specification has shown there are uncertainties regarding which modified peptide-carrier conjugates would have "increased peptide load and solubility"; see e.g. Para [0199][0200]; etc. In the argument, Applicants apparently acknowledge the uncertainties in peptide modification, but argue that "Those modified peptides that do not meet this claim limitation are outside of the scope of the claims". This argument is not convincing because the scope of the claims encompasses any peptides and any carriers of any structures. Neither Applicants' argument, nor the specification, has failed to indicate *which* modified peptides "do not meet this claim limitation" and "are outside of the scope of the claims". The rejection is therefore maintained.

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Remarks

10. No claims are allowed. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on Tu-F, 8:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/BO PENG/

Primary Examiner, Art Unit 1648